



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,598	01/18/2005	Stefano De Luigi Brushci	EURA-079/00US 307853-2271	2778
58249 7590 11/17/2009 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 11/17/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,598	Applicant(s) DE LUIGI BRUSHCI ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-41 is/are pending in the application.
- 4a) Of the above claim(s) 29-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-28 and 40-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims and specification filed 08/27/2009 have been entered. Any objection/rejection from the previous office action filed 02/27/2009 not addressed in the action below has been withdrawn.

Response to Arguments

Claims 15-17,19-21,23-24 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Percel et al. (US 6,451,345 B1), for the reasons set forth in the previous office action filed 02/27/2009.

Claims 15-24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Percel et al. (US 6,451,345 B1), for the reasons set forth in the previous office action filed 02/27/2009.

Applicant's arguments filed 08/27/2009 have been fully considered but they are not persuasive. Applicants assert that Percel cannot anticipate or render their claimed invention obvious because Percel only exemplifies Eudragit polymers such as L and S type that are soluble at higher pH and insoluble at lower pH whereas their presently claimed invention requires that the acrylic polymer is soluble at acidic pH.

The examiner respectfully disagrees. Firstly Percel teaches the use of methacrylic acid-methylmethacrylate and methacrylic acid-ethylmethacrylate copolymers which is clearly broader than just Eudragit type L and S polymers. Secondly while Percel does use Eudragit L in the examples, the examples within Percel were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit

Art Unit: 1618

and scope of the invention. Lastly Eudragit L is soluble above pH 6, as applicants are aware a pH that is less than 7 is acidic, thus since Eudragit L is soluble at a pH greater than 6 but less than 7 it is soluble at acidic pH. As evidence the examiner relies upon the teachings of Kotagale et al. (Pharmaceutical Development and Technology, 2009, pp 1-7), which clearly states that Eudragit L is soluble above pH 6, see page 2 second paragraph, left column.

Claims 15-17,19-20,23-28 and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Holt et al. (WO 00/30617), for the reasons set forth in the previous office action filed 02/27/2009.

Claims 15-28 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holt et al. (WO 00/30617), for the reasons set forth in the previous office action filed 02/27/2009.

The rejection of new claims 40-41 was necessitated by applicant's amendment. As described in the previous office action Holt teaches the use of Eudragit E type of polymers, from applicant's specification Eudragit E is a polymer that is soluble in 1N HCl. See pag 5 lin 24-26.

Applicants assert that Holt only exemplifies ethyl cellulose in combination with HPMC, HPMC applicants purport is a well known water soluble polymer and is now excluded from the first layer do to their transitional phrase "consists essentially of" ethylcellulose.

The relevance of this assertion is unclear. Clearly Holt describes the use of ethylcellulose as a material to be used as the spacer layer, the reference never states

Art Unit: 1618

that ethylcellulose must be present in a blend. While Holt may have had examples where ethylcellulose was used in combination with other polymers including HPMC **and** **PVP**, the examples within Holt were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Furthermore the transitional phrase “consisting essentially of” which limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention would not preclude additional polymers such as PVP and HPMC from being present unless they materially affected the basic or novel characteristic of the claimed invention. The examiner does not agree that PVP or HPMC are excluded due to the transitional phrase “consisting essentially of” since the examples use ethylcellulose as a coating and applicants first claimed layer appears to be no more than a coating itself. Thus PVP and HPMC are not seen as affecting the characteristic of applicants claimed layer since no unique properties are recited in the claim or in applicants arguments in which PVP or HPMC would materially affect the layer or coating which contains ethylcellulose.

Applicants further contend in regards to the 35 U.S.C. 103(a) rejection over Holt that it includes ethylcellulose in a laundry list of materials and provides no guidance on how to use ethylcellulose alone.

Once again the relevance of these assertions is unclear. The supposed laundry list on page 10 lines 3-7 disclose 11 different types of spacing materials, the examiner does not consider this to be a large laundry list of ingredients and one of ordinary skill in

Art Unit: 1618

the art would understand that any of the disclosed materials may be used as a spacing layer and know how to apply any of the materials to coat the core. Furthermore ethylcellulose would appear to be a more preferred material since its use is exemplified. As stated above the reference never recites that any of the spacing materials must be used in a blend. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed"... *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618